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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,229	06/26/2003	Manfred Bohn	3804.1596-01	4228
22852	7590	12/15/2006		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER KIM, VICKIE Y	
			ART UNIT 1618	PAPER NUMBER

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,229

Applicant(s)

BOHN ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-23 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-23 and 26-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/4/06 & 9/22/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 9/7/2006. Upon entering the amendment, the claims 14, 19 and 26 are amended.
2. The claims 14-23 and 26-29 are pending and presented for the examination.

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 9/22/06. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Response to Arguments

1. Applicant's arguments with respect to claims 14-23 and 26-29 have been considered but were not persuasive, furthermore, they are moot in view of the new ground(s) of rejection due to scope changes made into the claims.

The response to the applicant's argument is incorporated into the new ground rejection newly prepared. Since applicant's amendment is now been requiring new limitation "human subject" wherein that applicant's position found in argument was established based on *in vitro* study of secondary reference's(e.g. Squiquera) teaching, is, new ground of rejection is necessitated due to scope changes made into the claims.

It is also noted that applicant's argument is based on uncertainty in the field about the cause, or likely causes, of seborrheic dermatitis, it cannot be said definitively that seborrheic dermatitis is caused by *Pityrosporum*. However, the argument is not persuasive because the uncertainty of the etiology even adds the motivation to users to select ciclopirox as a drug of choice for the seborrheic dermatitis treatment because 2-hydroxy-2-pyridone (e.g. ciclopirox olamine) is well known as an antimycotic, antiseborrheic, and antidandruff agent in the state of the art in addition to same patient group is most likely benefited by the drug selection as evidenced by numerous documents including the references cited. Detailed rejection is following.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14-23 and 26-29 are under 35 U.S.C. § 103(a) as being unpatentable over Dittmar et al (U.S. 4,185,106) in view of Hanel et al(1991, abstract only) and medical dictionary or Ramachandran et al(US5834409), if necessary.

The claims are drawn to a method of treating seborrheic dermatitis in human patient using a single composition comprising a sole active agent consisting of at least one 1-hydroxy-2-pyridone of general formula I as recited in the claim 14, and at least one surfactant with pH of 4.5-6.5.

US'106 teaches an effective anti-dandruff treatment using a pharmaceutical composition containing 1-hydroxy-2-pyridones (e.g. ciclopirox(1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone) or octopirox(1-hydroxy-4-methyl-6-(2,4,4-trimethyl-pentyl)-2-

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pyridone)) as active agent, see abstract and col 2.

Applicant's claims differ because they are directed to a method of treating seborrheic dermatitis.

However, it would have been obvious to one of ordinary skill in the art at that time of the invention was made to extend the teaching to include seborrheic dermatitis when Dittmar(US'106) is taken in view of Hanel(1991) and medical dictionary or US5834409(if necessary) because latter references remedy the deficiency of Dittma's teaching.

Firstly, Hanel et al(1991) teach that antimycotic agent such as 1-hydroxy 2 pyridones(i.e. ciclopirox or rilopirox) effectively used in seborrheic eczema shown in human patients, see abstract.

It is noted that seborrheic eczema is alternative term for seborrheic dermatitis(see definitions of medical dictionary, PTO-892).

Hanel further teaches the significant therapeutic effectiveness achieved by ciclopirox(CIC, hereafter) where strong inhibition of inflammation and infiltration and flakiness has been obtained by CIC treatment in human patient. And thus, the deficiency of Dittmar is well remedied and one of ordinary skill in the art to select a composition containing 1-hydroxy 2-pyridones(e.g. CIC or rilopirox as a drug of choice) and a surfactant to treat seborrheic dermatitis effectively because the safety and

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therapeutic efficacy are well proven by references and the increased selection option increases industrial applicability where the main drawback factors associated with manufacturing antimycotic, antifungal and antibacterials the pharmaceutical product are resolved since the toxicities and safety are well proven by the cited references in addition to cost reduction (by avoidance of toxicity, efficacy studies) could benefit the users (patients).

All other critical elements (e.g. surfactant, pH, etc) required by the instant claims are well taught in the primary Dittmar reference. For example, Dittmar indirectly teaches weakly acidic composition which is desirable pH for hair composition, see col. 9, lines 28-29. Weakly acidic pH (pH around 4.5-6.5) is most desirable/suitable pH ranges for hair products, also well recognized in the pharmaceutical/cosmetic industries (see PTO-892 for supporting documents for pH selection commonly practiced in the industries, US3987161, US3996146, US5761824, US5834409). And thus, the claimed subject matter is not patentably distinct over the teaching of prior art of the record.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

1. No claim is allowed. Having carefully reviewed applicants' Request for Reconsideration, the examiner maintained the rejection in any respect.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Hartley reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
December 11, 2006
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